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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 8 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3592/FAP#8H5550. Abamectin (Avermectin B₁) on Citrus. Revisions to Section F and Enforcement Methodology. DEB Nos. 5509, 5510, 5629, 5630. MRID Numbers 41165300, -01.

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Tolerance Petition Section 2
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THRU: Richard D. Schmitt, Ph.D., Branch Chief
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Health Effects Division (H7509C) *Richard D. Schmitt*

TO: George LaRocca, PM 15
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and
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Background

Merck, Sharp and Dohme has proposed permanent tolerances for avermectin (AVM), including its delta-8,9-isomer, on citrus fruit, pulp, oil, cattle meat and meat byproducts, and milk at levels ranging from 0.001 to 0.10 ppm in the subject petitions. The tolerance requests have been reviewed and, after several revisions to the petition, resolution of the remaining deficiencies requires a revised Section F and revisions to the enforcement methodology (see memo of V.F. Boyd dated June 21, 1989).

Conclusions/Recommendations

The remaining DEB deficiencies related to this petition have been resolved as a result of this submission. TOX considerations permitting, DEB now recommends for the establishment of the following permanent tolerances for avermectin and its delta-8,9-isomer on citrus fruit, pulp, oil, cattle meat and meat byproducts:

<u>Commodity</u>	<u>Tolerance</u>
Citrus whole fruit (RAC)	0.02 ppm
Cattle - meat and mbyp	0.02 ppm
Milk	0.005 ppm
Dried citrus pulp	0.10 ppm
Citrus oil	0.10 ppm

Present Considerations

The petitioner has submitted a response to the remaining deficiencies as outlined in the DEB memo of V.F. Boyd dated June 21, 1989.

The deficiencies are summarized here, followed by the petitioner's response and DEB's comments and conclusions.

Deficiency 4b

DEB requests from the petitioner a copy of Method 1009 No. 2 (citrus RAC method) incorporating that portion of Method 1004R02 (process commodity method) necessary to accommodate analysis of the processed commodities of citrus. This method copy will be submitted to FDA for inclusion in PAM II as the enforcement method for citrus and its processed commodities.

Petitioner's Response to Deficiency 4b

The petitioner has submitted a revised enforcement method (MRID No. 411653-01). The method for citrus fruit and the method for citrus process fractions have been combined (Method No. 1009R03). The alternate cleanup procedures outlined for citrus process fractions are now incorporated in the procedures for citrus fruit.

DEB's Comments/Conclusions, re: Deficiency 4b

This deficiency is resolved.

Deficiencies 5b, 6b, and 7b (paraphrased)

5b. The residue data show levels of avermectin B₁ and its delta 8,9-isomer in citrus as:

oranges	- <0.002 - 0.011 ppm
grapefruit	- <0.002 ppm
tangelos	- <0.002 ppm
lemons	- <0.002 ppm

Since finite residues in CA oranges are reported as 0.008 and 0.011 ppm, then a proposed tolerance of 0.005 ppm would be inadequate for the proposed use. A tolerance level of 0.02 ppm for the RAC citrus would appear appropriate.

6b. The processing study data show a concentration factor of 5X from citrus RAC to dried peel and oil. When this factor is applied to a proposed tolerance of 0.02 ppm, then an adequate tolerance for dried citrus pulp and oil would be 0.10 ppm. An increased proposed tolerance will be necessary for dried pulp.

7b. The proposed tolerances on meat and meat byproducts (0.005 ppm) and milk (0.001 ppm) are considered inadequate due to the necessity for increased tolerances for citrus RAC and feed items. A new section F proposing tolerances of 0.02 ppm for cattle meat and meat byproducts, and 0.05 ppm for milk would seem appropriate.

Petitioner's Response to Deficiencies 5b, 6b, and 7b

The petitioner has submitted a revised Section F as a part of a correspondence from Louis Grosso of Merck, Sharp and Dohme dated June 20 1989. The revisions are as follows:

<u>Commodity</u>	<u>Proposed Tolerances (ppm)</u>	
	<u>Initial Section F</u>	<u>Revised Section F</u>
citrus fruit	0.005	0.02
cattle - meat and mbyb	0.005	0.02
milk	0.001	0.005
dried citrus pulp	0.03	0.10
citrus oil	0.10	0.10

The section F now requests the tolerance levels for citrus fruit, pulp, oil, and animal commodities that were determined necessary by DEB.

DEB's Comments and Conclusions, re: Deficiencies 5b, 6b, 7b

Deficiencies 5b, 6b, and 7b are resolved.

cc: Circ., RF, PP#8F3592/FAP#8H5550, Willett, PMSD/ISB (Eldredge)
H7509C:DEB:CM2:RM810:SHW:shw-8/4/89:557-1439
RDI: D. Edwards, 8/7/89